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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,274	01/23/2002	Dee H. Wu	PKR 2 0716	6763
7590 09/08/2004				
Thomas E. Kocovsky, Jr. FAY, SHARPE, FAGAN, MINNICH & McKEE, LLP 1100 Superior Avenue, Seventh Floor Cleveland, OH 44114-2518				
EXAMINER SHAW, SHAWNA JEANNINE				
ART UNIT 3737		PAPER NUMBER		
DATE MAILED: 09/08/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	Application No. 10/055,274	Applicant(s) WU ET AL.	
	Examiner Shawna J. Shaw	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 January 2002 and 09 February 2004.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-22 and 24-29 is/are rejected.
- 7) ☒ Claim(s) 10 and 23 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/23/02 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>01232002, 02092004</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 1 and 13 are objected to because of the following informalities: It is not clear from the claims whether the 'acquiring/constructing a parametric map' and 'determining/identifying piloting information' steps are intended to take place during the same imaging procedure as the 'administering a contrast agent' and 'imaging during a transient distribution/influx' steps - or whether they can also take place during separate, procedures. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

### ***Claim Rejections - 35 USC § 103***

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 2, 4-9, 11-14, 16-22 and 24-29 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wu et al.

"Myocardial Perfusion" of record.

Regarding claims 1, 2, 4-9, 11-14, 16-22 and 24-27, Wu et al. disclose acquiring a  $T_2^*$  parametric map (fig. 2), determining piloting information based on blood oxygenation (BOLD) contrast of the parametric map (p. 1, first column, p. 2 first column) to pilot administration of a contrast agent to the patient and imaging a transient distribution thereof using first pass or late enhancement techniques (fig. 1, p. 1-2). Wu et al. additionally disclose administering a pharmacological stress agent (which also acts as a second contrast agent) to enhance the BOLD image. Wu et al. further disclose fusing, or registering, the BOLD and FPM images. Wu et al. does not explicitly address performing BOLD and FPM sequentially in the same procedure, but it is not clear from the claimed invention that the steps of acquiring the piloting information and imaging during a transient distribution of contrast agent must take place in the same imaging procedure. However, Wu et al. does disclose that multiple echo techniques can overcome previous limitations to BOLD and first pass methods and that recognizes

BOLD and FPM scans can be combined to improve both quantitative and qualitative evaluation of tissue viability. It would have therefore been obvious at the time the invention was made to a person of ordinary skill in the art to use the two techniques in the same procedure for the above reasons. Further regarding claims 28 and 29, although Wu et al. do not explicitly disclose obtaining the pixel intensity decay time constant or rate map by regression or statistical analysis, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use regression or statistical analysis because Applicant has not disclosed that such techniques provide an advantage, are used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the pixel intensity decay time constant or rate map obtained by Wu et al.

3. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. "Myocardial Perfusion" of record in view of Sechtem et al. 'Stress Functional MRI : Detection of Ischemic Heart Disease and Myocardial Viability' of record.

Regarding claim 3, Wu et al. differ from the claimed invention in that the type of stress-causing agent is not explicitly addressed. Sechtem et al. generally disclose that dobutamine has become the drug of choice for pharmacologic stress testing using MRI (p. 667, 2<sup>nd</sup> col). It would have therefore been obvious at the time the invention was made to a person of ordinary skill in the art to use a stress-causing agent such as dobutamine in the invention as taught by Wu et al. as is well recognized in the art.

4. Claims 1, 4, 13, 15, 17, 18, 19, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carroll in view of WO 99/63355.

Regarding claims 1, 4, 8, 13, 15, 17, 18, 19, 26 and 27, Carroll disclose a method and apparatus for performing contrast enhanced and diffusion-weighted MRI time course imaging of the brain including obtaining hemodynamic parameter/activation maps. See [0007-9], [0038], [0060]. Carroll differs from the claimed invention however in that piloting information is not explicitly addressed. WO 99/63355 generally teaches the use of hemodynamically-weighted brain activation maps for interactively piloting dynamic contrast enhancement images to a specific field of view or desired resolution during a single session. See p. 6 line 30 – p. 7 line 20, p. 12 lines 7-12 and p. 15 lines 17-21. It would have been obvious at the time the invention was made to a person of ordinary skill in the art to use the acquired hemodynamically-weighted pre-contrast images Carroll for piloting the dynamic contrast enhancement images, as taught by WO 99/63355 so as to achieve improved spatial and/or temporal resolution and cost effectiveness.

***Allowable Subject Matter***

5. Claims 10 and 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gupta et al. (6,687,528) and Lang et al. (5,671,741) teach away


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from the use of exogenous contrast agents. Wu et al. (6,687,527) disclose an MRI parameter optimization system and method.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawna J. Shaw whose telephone number is (703) 308-2985. The examiner can normally be reached from 6:45 a.m. – 3:15 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Shawna J. Shaw  
Primary Examiner  
Art Unit: 3737  
09/02/2004